

REMARKS

Status of the Claims

Claims 18-37 are pending. Claims 1-17 have previously been cancelled. Claims 18-37 have been rejected. Claims 32 and 33 are allowable. Claims 18-27 have been cancelled. Claim 35 has been amended. Reconsideration of the application is respectfully requested.

Objection to the Drawings

The drawings are objected to under 37 CFR 1.83(a) as not showing every feature of the invention specified in the claims. Claim 27 has been cancelled and Claim 35 has been amended. Applicant respectfully requests that the objection to the drawings has been rendered moot and should be withdrawn.

The Rejections Under 35 U.S.C. §112, First Paragraph Should be Withdrawn

Claims 18-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that there is no support in the specification for previously amended Claim 18 which requires the simultaneous collecting of fluid samples from at least two ductal networks. The Applicant respectfully disagrees.

Page 17, lines 25-34, and in particular lines 25-28 state that “[t]he methods of accessing more than one breast duct occur using the apparatus of the invention such that all the ducts that the practitioner desires to access are accessed and the substance delivered (and/or collected in the case of a lavage procedure) at approximately the same time, i.e. in the same procedure or simultaneously.” The specification clearly contemplates the simultaneous delivery and collection of fluid to a breast duct. The Applicant would also like to point out that the term “simultaneous” has been defined in the specification as meaning at the same time or about the same time (see page 18, lines 1-10). The Examiner questions whether the method of the present

invention is practical because "...simultaneous collection would require 9-12 people." Setting aside whether a method is difficult to accomplish is the proper standard for a rejection under 35 U.S.C. 112, first paragraph, since, as mentioned previously, simultaneous has been defined by the Applicant as meaning that the collection of samples can be accomplished during the same procedure, it is not necessary that collection of samples from the 9-12 breast ducts would require 9-12 pairs of hands. Once the breast ducts have been filled with fluid, the collection of the fluid can take place either all at once or, in the alternative, from each individual breast duct consecutively, as long as the collection takes place while the probes remain within the breast ducts.

Although the Applicant believes that the rejections to Claims 18-27 under 35 U.S.C. 112, first paragraph have been traversed, in order to expedite prosecution, Claims 18-27 have been cancelled thus rendering the Examiner's rejection moot. Withdrawal of the rejection is requested.

The Rejections Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 18-24, 28-30, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Jeter *et al.* (USP No. 5,683,420). The examiner maintains that the structure recited by the prior art is identical to the claimed structure. Applicants traverse this rejection.

Claims 18-27 have been cancelled thus rendering the Examiner's objection moot as it applies to Claims 18-24. As for Claims 28-30, 36 and 37, the Applicant disagrees that the present invention is anticipated by Jeter *et al.* The Examiner states that "[r]egarding claim 28, see Jeter figure 3. Jeter feed septum 14 anticipates the manifold; container 12 anticipates the collection tube." (see page 4, last paragraph). Without addressing the Examiner's assertion that the feed septum [14] of Jeter anticipates the manifold and the container [12] of Jeter anticipates

the collection tube of the present invention, the Examiner has not addressed one of the limitations of Claim 28 which requires a “collection tube connected to at least one probe for receiving biological material from within the breast.” Jeter does not teach or suggest a collection tube connected to at least one probe. Figure 3 of Jeter depicts a container [12] connected to the feed septum [14], not to any of the access probes [13] of Jeter. The advantage of having a collection tube connected to at least one probe potentially allows the apparatus of the present invention to collect fluid from each individual duct from a patient without the mixing of samples from other ducts. This would allow the determination of the presence of cancerous or pre-cancerous cells or other markers in an individual breast duct. The apparatus of Jeter clearly does not have such a capacity. Thus Claims 28-37 are not anticipated by Jeter *et al.*.

Accordingly, for the reasons stated above, Claim 28 and all claims depending therefrom (29-30, 36 and 37) are allowable. Withdrawal of the rejection is requested.

The Rejections Under 35 U.S.C. §103(a) Should be Withdrawn

Claims 26, 27, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeter *et al.* (USP No. 5,683,420). The Applicant respectfully traverses this rejection.

Claims 18-27 have been cancelled thus rendering the Examiner’s rejection moot as it applies to Claims 26 and 27. As for Claims 34 and 35, the Applicant restates the argument made above that Jeter *et al.* either alone or in combination, does not teach or suggest a collection tube connected to at least one probe for receiving biological material from within the breast. The ability of the apparatus to be separable is not relevant and needs not to be addressed since Jeter *et al.* either alone or in combination, does not teach or suggest all the limitations of the present invention. Thus, Claims 34 and 35 are not rendered obvious by Jeter *et al.*

For all of the above-discussed reasons, Applicant submits that the rejection of Claims 34 and 35 under 35 U.S.C. §103(a) have been overcome. Withdrawal of the rejection is requested.

Rejection Under the Judicially Created Doctrine of Obviousness-Type Double Patenting

Applicant asserts that a terminal disclaimer may be filed at the time the claims are indicated to be allowable. Applicants appreciate the examiner holding this issue in abeyance until such a time that there is allowable subject matter.

Conclusion

In light of the amendments and arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.025011.

Respectfully submitted,

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